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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/474,388	06/07/95	SPRINGER T	1011.004000D

EXAMINER
CUNNINGHAM, T

18N1/0807

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ART UNIT	PAPER NUMBER
1816	

DATE MAILED: 08/07/96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/474,388	Springer et al.
Examiner	**Group Art Unit**
Thomas M. Cunningham	1816

☒ Responsive to communication(s) filed on *Feb 6, 1996* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-70* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-70* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-6 and 11, drawn to ICAM-1 proteins, classified in Class 530, subclass 395.

Group II. Claims 7-8, drawn to nucleic acids, classified in Class 536, subclass 23.1.

Group III. Claims 9-10, drawn to methods of recovering ICAM-1, classified in Class 530, subclass 412.

Group IV. Claims 12-14 and 65-66, drawn to antibodies (or hybridomas) to ICAM-1, classified in Class 530, subclass 388.23 or Class 435, subclass 240.27.

Group V. Claim 15 directed to a method of identifying non-immunoglobulin antagonist of ICAM-1, classified in Class 436, subclass 501.

Group VI. Claims 16-34, 35-53 and 69-70, drawn to methods of treatment or pharmaceutical compositions, classified in Class 424, subclass 143.1 or 185.1.

Group VII. Claims 54-64 and 67-68, drawn to diagnostic methods, classified in Class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the ICAM-1 product may be made by recombinant DNA techniques as well as by chemical synthesis.

3. Inventions I, II and IV are disclosed as different combinations which are not connected in design, operation or effect. These combinations are independent if it can be shown that (1) they are not disclosed as capable of use together, (2) they have different modes of operation, (3) they have different functions, or (4) they have different effects. (MPEP 806.04, MPEP 808.01). In the instant case the combinations are directed to structurally and functionally distinct chemical compounds: ICAM-1 proteins, DNA and antibodies.

4. Inventions I; and IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the ICAM-1, LFA-1 or antibody products may be used either therapeutically or

diagnostically. Alternatively, the claimed methods may be practiced with structurally distinct ICAM-1, LFA-1 or antibody species.

5. Inventions III, V, VI and VII are disclosed as different combinations which are not connected in design, operation or effect. These combinations are independent if it can be shown that (1) they are not disclosed as capable of use together, (2) they have different modes of operation, (3) they have different functions, or (4) they have different effects. (MPEP 806.04, MPEP 808.01). In the instant case the methods of each group have materially different steps encompassing different functions and modes of operation required for either identification of ICAM-1 antagonists, therapeutic treatment or diagnosis.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Should Applicant elect either Group VI or VII an election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention: the methods of Groups VI and VII recite use of structurally distinct products encompassing different domains of ICAM-1, non-immunoglobulin antagonists of ICAM-1 (such as LFA-1) and anti-ICAM-1 antibodies.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 16 is generic for Group VIand no claim is generic for Group VII.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicant should elect a single type of product, i.e. an ICAM-1 species (e.g. domain 1-2 of ICAM-1), LFA-1 or antibody to ICAM-1. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. A telephone call was made to Bob Millonik on 7/29/96 and on 8/5/96 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant requested a written restriction on 8/5/96.

10. This application may be subject to the transitional restriction provisions of Public Law 103-465, which became effective on June 8, 1995, because:

1. the application was filed on or before June 8, 1995, and has an effective U.S. filing date of June 8, 1992, or earlier;
2. a requirement for restriction was not made in the present or a parent application prior to April 8, 1995; and
3. the examiner was not prevented from making a requirement for restriction in the present or a parent application prior to April 8, 1995, due to actions by the applicant.

The transitional restriction provisions permit applicant to have more than one independent and distinct invention examined in the same application by paying a fee for each invention in excess of one.

Final rules concerning the transition restriction provisions were published in the *Federal Register* at 60 FR 20195 (April 25, 1995) and in the *Official Gazette* at 1174 OF 15 (May 2, 1995) and at 37 CFR 1.17(s) include the fee amount required to be paid for each additional invention as set forth in the following requirement for restriction.

Applicant must either:(1) elect the invention or inventions to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) for each independent and distinct invention in excess of one which applicant elects; or (2) file a petition under 37 CFR 1.129(b) traversing the requirement.

11. Papers related to this application may be submitted to Group 1800 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Thomas Cunningham, Art Unit 1816 and should be marked either "OFFICIAL" for entry into the prosecution history or "DRAFT" for consideration by the Examiner without entry. The Art Unit 1816 FAX telephone number is (703) 305-7939. FAX machines will be available to receive transmissions 24 hours a day.

12. In compliance with 1096 OG 30 the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or federal

holiday with the District of Columbia, in which case the official date of receipt will be the next business day.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas M. Cunningham, Ph.D, J.D. whose telephone number is (703) 308-3968. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

TMC

THOMAS M. CUNNINGHAM
PRIMARY EXAMINER
GROUP 1800